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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,357	11/17/2003	Hans Nilsson	06275-081003	7635

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EXAMINER	
GEORGE, KONATA M	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental Notice of Allowability	Application No. 10/716,357	Applicant(s) NILSSON ET AL.	
	Examiner Konata M. George	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Terminal Disclaimer filed February 17, 2005*.

2. ☒ The allowed claim(s) is/are *27-103*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Claims 27-103 are pending in this application.

Action Summary

1. The rejection of claims 28-32, 36-47, 57-69 and 72-83 under 35 U.S.C. 112, first paragraph as not described in the specification as to enable one skilled in the art to make and/or use the invention is hereby by withdrawn as applicant has amendment the claims to clearly define what type of condition is being treated.

2. The rejection of claims 40-43, 57-65 and 78-80 under 35 U.S.C. 112, first paragraph as not described in the specification as to enable one skilled in the art to make and/or use the invention is hereby by withdrawn as per our interview.

3. The rejection of claims 27-94 under the judicially created doctrine of obviousness-type double patenting over claims 1-29 of US Patent 6,291,445 B1 is hereby withdrawn as applicant has filed a terminal disclaimer.

4. The rejection of claims 27-94 under the judicially created doctrine of obviousness-type double patenting over claims 1-29 of US Patent 6,686,346 is hereby withdrawn as applicant has filed a terminal disclaimer.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should that changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mrs. Janis Fraser on June 27, 2005.

Amend the claims as follows:

IN THE CLAIMS:

In claims 32, 39, 47, 69, 74 and 83, line 1, **delete** "wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide." and **insert** "wherein the concentration of budesonide in each unit dose is about 0.6 to 0.7 mg/ml."

In claims 43, 65 and 80, line 1, **delete** "wherein the unit dose contains about 0.6 to 0.7 mg/ml budesonide." and **insert** "wherein the concentration of budesonide in the unit dose is about 0.6 to 0.7 mg/ml."

In claim 51, line 1, **delete** "wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide." and **insert** "wherein the concentration of budesonide in the unit dose is about 0.6 to 0.7 mg/ml."

In claim 52, line 2, **insert** ", at least 90% of which have a mass equivalent sphere diameter of less than 20 μm," **after** "...finely divided particles".

In claim 55, line 1, **delete** "wherein the composition contains about 0.6 to 0.7 mg/ml budesonide." and **insert** "wherein the concentration of budesonide in the composition is about 0.6 to 0.7 mg/ml."

In claim 57, line 4, **insert** ", at least 90% of which have a mass equivalent sphere diameter of less than 20 μm," **after** "...finely divided budesonide particles".

In claim 66, line 5, **insert** ", at least 90% of which have a mass equivalent sphere diameter of less than 20 μm," **after** "...finely divided budesonide particles".

In claim 70, line 9, **insert** ", at least 90% of which have a mass equivalent sphere diameter of less than 20 μm," **after** "...finely divided particles".

In claim 72, line 12, **insert** ", at least 90% of which have a mass equivalent sphere diameter of less than 20 μm," **after** "...finely divided particles".

In claim 75, line 2, **insert** ", at least 90% of which have a mass equivalent sphere diameter of less than 20 μm," **after** "...finely divided particles".

In claim 77, line 1, **delete** "wherein the composition contains about 0.6 to 0.7 mg/ml budesonide." and **insert** "wherein the concentration of budesonide in the composition is about 0.6 to 0.7 mg/ml."

In claim 78, line 4, **insert** ", at least 90% of which have a mass equivalent sphere diameter of less than 20 μm," **after** "...finely divided particles".

In claim 81, line 5, **insert** ", at least 90% of which have a mass equivalent sphere diameter of less than 20 μm," **after** "...finely divided particles".

In claim 84, line 10, **insert** ", at least 90% of which have a mass equivalent sphere diameter of less than 20 μm," **after** "...finely divided particles".

In claim 87, line 1, **delete** "wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide." and **insert** "wherein the concentration of budesonide in the composition is about 0.6 to 0.7 mg/ml."

Authorization for this examiner's amendment was given in a telephone interview with Mr. Larry Dhang on August 26, 2005.

In claim 40, line 1, delete "or preventing"

In claim 57, line 1, delete "or preventing"

Statement of Reasons for Allowance

6. The following is an examiner's statement of reasons for allowance:
The claims are allowable over the prior art because the prior art does not teach, disclose nor make obvious a unit dosage form comprising 16-40 μg budesonide with a 90% mass equivalent and a diameter of less than 20 μm and suspended in an aqueous medium. The prior art does not teach or disclose a dosage form of budesonide having the above-mentioned limitations.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

7. Claims 27-103 are allowed.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600